UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

RICHARD CONNELLY,

Plaintiff,

v.

ST. JUDE MEDICAL, INC., et al.,

Defendants.

Case No. 5:17-cv-02006-EJD

ORDER GRANTING DEFENDANTS' RENEWED MOTION TO DISMISS PLAINTIFF'S FAILURE-TO-WARN CLAIM

Re: Dkt. No. 45

Plaintiff Richard Connelly ("Connelly" or "Plaintiff") brings claims against Defendants St. Jude Medical, LLC, Abbott Laboratories, and Pacesetter, Inc. (collectively, "St. Jude" or "Defendants") arising from injuries he suffered from allegedly defective medical devices. In a First Amended Complaint ("FAC"), Connelly re-pleads, among other things, a cause of action for strict liability—failure to warn. FAC ¶¶ 103-16, Dkt. No. 41. St. Jude moves to dismiss under Fed. R. Civ. P. 8(a) and 12(b)(6) on the grounds that Connelly's claims are insufficiently pled. Mot. to Dismiss ("MTD"), Dkt. No. 45. The Court finds this matter suitable for decision without oral argument. Civ. L.R. 7-1(b). For the reasons discussed below, St. Jude's motion will be GRANTED.

I. BACKGROUND

A. Factual Background

The factual background of this case is set forth in the Court's order regarding St. Jude's motion to dismiss Connelly's original Complaint. Dkt. No. 38. For clarity, the Court reviews facts as alleged in the FAC below:

In 1976, Congress enacted the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). The MDA gave the Food and Drug Administration ("FDA") authority to regulate medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008).

Medical devices that support human life, or pose a high risk of illness or injury, are known as Class III devices. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). Manufacturers must apply for and receive premarket approval ("PMA") from the FDA before they can sell Class III devices. *Id.* The FDA grants approval after a rigorous review process. *Riegel*, 552 U.S. at 317. After a device has received approval, the manufacturer may not make changes that would affect the device's safety or effectiveness without applying for and receiving supplemental approval (a "PMA Supplement") from the FDA. *Id.* at 319. The manufacturer is required "to report incidents [to the FDA] in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." *Id.*

St. Jude manufactures Class III devices called Riata Leads. FAC ¶¶ 1, 32. Riata Leads allow an implantable cardiac defibrillator ("ICD") to detect a patient's abnormal heartbeat and deliver an electric shock to restore a normal heartbeat. *Id.* ¶ 1.

In 1996, the FDA approved St. Jude's PMA application for an ICD lead called the Ventritex VTI Lead. *Id.* ¶ 34. St. Jude sought and obtained supplemental approval several times in the following years. *Id.* ¶¶ 34-35. In 2002, the FDA approved St. Jude's fourteenth PMA Supplement, which approved design modifications and allowed the leads to be marketed under the Riata name. *Id.* ¶ 35.

Connelly alleges that his doctors surgically installed Riata Leads and connected them to his heart in May 2003 (and again in 2007 and 2015). *Id.* ¶¶ 3, 87-90. Connelly underwent this surgery based on the advice of two cardiologists who he saw starting in 2002. *Id.* ¶ 86. Connelly alleges that one of these cardiologists was a "specialist in pacemaker and ICD implants" who

"would have tracked the [FDA's Manufacturer and User Facility Device Experience ("MAUDE")[1] database] for problems with the Ventritex TVI and Riata Leads and all competitors before recommending any implant to Mr. Connelly." *Id.*

Starting in October 2005, St. Jude conducted an internal audit to examine "inside-out abrasion" associated with malfunctioning Riata Leads. *Id.* ¶¶ 56-57. The "audit concluded that Riata Leads had potentially serious insulation problems." *Id.* ¶ 58. In 2009, the FDA conducted an inspection of St. Jude's facilities. *Id.* ¶ 59. As a part of this audit, the FDA requested a list of all Corrective and Preventative Action ("CAPA") and Product Improvement Requests ("PIR") opened since 2002. *Id.* Connelly alleges that the FDA inspection "revealed that Defendants had deficiencies in the handling of complaints, making Medical Device Reporting ('MDR') determinations, Corrective and Preventative Action ('CAPA') procedures, and receiving protocols." *Id.* ¶¶ 35, 56, 60. As a result of the investigation, the FDA issued a "Form 483 report" that identified possible "violation[s] of the FDCA and related Acts." *Id.* ¶ 63.

In 2010, St. Jude published a "Dear Doctor" letter that identified defects in certain Riata Lead models, including the model that was implanted in Connelly. *Id.* ¶ 72. St. Jude published an updated letter in November 2011. *Id.* ¶ 76. In December 2011, the FDA reclassified the letter as a product recall, indicating that "failures associated with lead insulation abrasion on the St. Jude Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become externalized. If this occurs, this product may cause serious adverse health consequences, including death." *Id.* ¶¶ 77.

Connelly alleges that, in November 2016, his Riata leads malfunctioned while he slept. *Id.* ¶ 91. He "was shocked an estimated sixteen to twenty times, causing irreparable harm to his heart, body, and mind." *Id.* He underwent surgery in March 2017 to replace the faulty lead.

[1] The MAUDE is a voluntary reporting system in which the FDA lists adverse-event reports received from device manufacturers. *Id.* ¶ 78; MTD 5. Manufacturers are required by law to report device-related adverse events. *Id.*; *see* 21 U.S.C. § 360i(a)(1). The FDA also "may disclose" adverse-event reports on the MAUDE, but it is not required to do so. 21 C.F.R. § 803.9(a).

Id. ¶ 95.

B. Procedural Background

Connelly initiated this suit on April 11, 2017. Compl., Dkt. No. 1. In his original complaint, Connelly brought causes of action for (1) strict liability—manufacturing defect (Compl. ¶¶ 97-103), (2) strict liability—failure to warn (Compl. ¶¶ 104-15), (3) negligence per se (Compl. ¶¶ 116-23), and (4) negligence (Compl. ¶¶ 124-29). St. Jude moved to dismiss, Dkt. No. 29, which the Court granted in part and denied in part with leave to amend, Dkt. No. 38 ("MTD Order"). Among the claims dismissed was Connelly's claim for strict liability—failure to warn, which the Court dismissed because Connelly had not sufficiently alleged a causal link between St. Jude's alleged failure to warn and Connelly's injuries. MTD Order 8.

Connelly filed his FAC on September 8, 2017. Dkt. No. 41. In his FAC, Connelly alleges causes of action for (1) strict liability—manufacturing defect (FAC ¶¶ 96-102), (2) strict liability—failure to warn (FAC ¶¶ 103-16), and (3) negligence (FAC ¶¶ 117-23). St. Jude now moves to dismiss Connelly's second claim for strict liability—failure to warn. Dkt. No. 45.

II. LEGAL STANDARD

A motion to dismiss under Fed. R. Civ. P. 12(b)(6) tests the legal sufficiency of claims alleged in the complaint. *Parks Sch. of Bus., Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Dismissal "is proper only where there is no cognizable legal theory or an absence of sufficient facts alleged to support a cognizable legal theory." *Navarro v. Block*, 250 F.3d 729, 732 (9th Cir. 2001). The complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

III. DISCUSSION

The Ninth Circuit has recognized a "narrow gap" through which a state law claim—such as Connelly's strict liability claim here—will not be impliedly preempted by the FDCA. *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). "To properly plead parallel [state law] claims that survive preemption, a plaintiff must allege facts (1) showing an alleged violation of FDA

regulations or requirements related to [the device], and (2) establishing a causal nexus between the alleged injury and the violation." *Houston v. Medtronic, Inc*., 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013) (quoting *Erickson v. Boston Scientific Corp*., 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011)) (internal quotation marks omitted).

Manufacturers of Class III devices have a duty to "report incidents [to the FDA] in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." *Riegel*, 552 U.S. at 319. Here, Connelly alleges that "from 1997 through at least November 2016, Defendants failed to comply with their duty to file adverse-event reports with the FDA and, at the same time, breached their state law duty to warn of dangerous product defects." Opp'n 8, Dkt. No. 48; FAC ¶¶ 106-07, 110-12. Connelly alleges that these failures caused his injury in two ways: (1) if St. Jude had not failed to submit adverse-event reports to the FDA prior to the implantation of Riata Leads (in May 2003), Connelly's surgeon never would have implanted them; and (2) if St. Jude had not failed to submit adverse-events reports to the FDA after implantation, Connelly's surgeon would have removed them prior to the November 2016 malfunction. Opp'n 11-13; FAC ¶¶ 107, 113.

In its order dismissing Connelly's failure to warn claim, the Court found that Connelly had failed to allege a causal connection between his injuries and St. Jude's failure to warn. MTD Order 8. Connelly's allegations in the FAC suffer from this same deficiency.

First, as to Connelly's first theory of injury—that Connelly's surgeon never would have implanted the Riata Leads but for St. Jude's alleged failure—Connelly again fails to allege any facts that plausibly establish a causal nexus. As was the case with all of Connelly's allegations in his original Complaint, most of Connelly's allegations in the FAC refer to adverse events that occurred after the Riata Leads were implanted in him (in 2003). *See* FAC ¶¶ 8 ("No later than 2005 and likely sooner, St. Jude realized the Riata Leads were defective."), 56-58 (primarily referring to incidents that occurred in 2005 and 2008), 60-62 (referring to results of FDA inspections that were made available in 2009 and cover a period running from 2002), 74 (referring

to a 2010 Dear Doctor letter). The only specific allegation that Connelly makes regarding adverse events that occurred prior to the 2003 implantation is that the 2009 FDA inspection, which covered a period starting from 2002, "revealed that Defendants had deficiencies in the handling of complaints, making [MDR] determinations, [CAPA] procedures, and receiving protocols." FAC ¶¶ 35, 56, 60. However, Connelly alleges no facts regarding whether any of these "deficiencies in the handling of complaints . . ." occurred in 2002-03, related to the Riata Leads (and, specifically, the abrasion malfunction that allegedly caused his injuries), or actually amounted to failures in reporting. In short, Connelly fails to allege anything more than a speculative connection between the 2009 FDA inspection and potentially unreported adverse events.

Moreover, judicially noticeable materials[2] relating to the 2009 FDA inspection confirm the speculative nature of Connelly's allegation. According to the Establishment Inspection Report ("EIR") issued by the FDA upon completion of the 2009 inspection, the primary focus of the inspection was on malfunctions relating to perforation—not abrasion. *See* Taubert Decl., Ex 1., Dkt. No. 45-2 ("EIR"), at 5-8. At least for perforation events, the FDA concluded that it "did not identify any adverse events that failed to be reported." *Id*. at 13. It identified two adverse events that were reported significantly past the mandatory reporting timeframes, but neither of these were reported prior to May 2013. *Id*. at 18. Given this, the possibility that there were relevant pre-implantation adverse events seems even more attenuated. Accordingly, Connelly's allegation regarding the 2009 FDA inspection cannot form a plausible basis for his pre-implantation theory.

Connelly's remaining allegations regarding adverse effects fare no better. For example, Connelly alleges that "St. Jude was informed by physicians of several incidents where, as a result of abrasion from the inside-out of the lead wires, St. Jude defibrillators sent unnecessary jolts to

[2] The Court takes judicial notice of the FDA's Establishment Inspection Report ("EIR") because it is a "matter of public record" whose content is "not subject to reasonable dispute" and "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001) (quoting *Mack v. S. Bay Beer Distrib.*, 798 F.2d 1279, 1282 (9th Cir. 1986)); Fed. R. Evid. 201(b). In addition, it appears that Connelly's complaint "necessarily relies on it," as the allegation of FAC ¶ 59 mirrors language in the EIR. *Compare* FAC ¶ 59, *with* EIR 9.

the heart or failed to deliver lifesaving shocks to return chaotic heart rhythms back to normal." FAC ¶ 56. However, these are simply "'naked assertions' devoid of 'further factual enhancement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555, 557). As such, they also do not plausibly establish any pre-implantation adverse events that could form the basis for Connelly's claim.

Second, as to Connelly's second theory of injury—that Connelly's surgeon would have removed the Riata Leads but for St. Jude's alleged failure—, this too lacks a causal nexus. Although Connelly's allegations reference adverse events that occur within the relevant timeframe (2003-16), Connelly alleges no facts that would establish any causal nexus between alleged failures to report these events and his injury. The only allegation he makes with respect to this second theory is that "[h]ad Defendants not breached their duty to warn, relevant information relating to the safety and efficacy of the Riata Leads would have reached Plaintiff's doctors, and would have caused Plaintiff to extract the device, prior to Plaintiff suffering the repeated, violent electrical shocks, as alleged above." FAC ¶ 113. However, this is conclusory and insufficient as a matter of law. Moreover, if anything, the factual allegations in the FAC—even construed in the light most favorable to Connelly—suggest the opposite. Despite St. Jude's 2010 and 2011 Dear Doctor letters and the FDA's 2011 Class I Recall reclassification, FAC ¶¶ 74-77, Connelly's doctor decided to not replace the Riata Leads when Connelly underwent surgery in 2015, FAC ¶ 90. This suggests that, even if St. Jude had not allegedly failed to report adverse events, it would not have caused Connelly's surgeon to remove the Riata Leads. As such, Connelly has not plausibly alleged a causal nexus.

Moreover, to the extent Connelly's claim is premised on a theory that St. Jude had a post-distribution (i.e., post-implantation) duty to warn, this fails as a matter of law. Under California law, a defendant may be held strictly liable for a failure to warn only if "the defendant did not adequately warn of a particular risk that was known or knowable . . . at the time of manufacture and distribution." *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 558 (Cal. 1991) (emphasis added). Accordingly, Connelly's second theory is problematic for this reason as well.

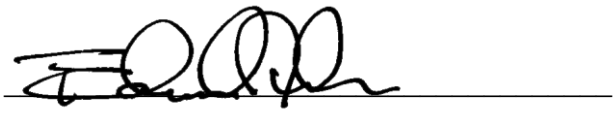
In sum, Connelly has not plausibly alleged a causal connection between his injuries and St. Jude's failure to warn. Accordingly, his claim will be DISMISSED. Further, since this was Connelly's second opportunity to plead this claim and Connelly's second attempt fails for the same reasons as before, *see* MTD Order 8, this claim will be dismissed without leave to amend as allowing for further amendment would be futile. *Miller v. Rykoff-Sexton*, 845 F.2d 209, 214 (9th Cir. 1988) ("A motion for leave to amend may be denied if it appears to be futile or legally insufficient.").

IV. ORDER

St. Jude's motion to dismiss is GRANTED. Connelly's claim for failure to warn will be DISMISSED without leave to amend.

IT IS SO ORDERED.

Dated: February 6, 2018



EDWARD J. DAVILA
United States District Judge

United States District Court
Northern District of California